

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/797,879 Confirmation No.: 5083
Applicant : Mel R. Beulke
Filed : March 10, 2004
TC/A.U. : 3773
Examiner : Erez, Darwin P.
Title : REMOVABLE INTRAVASCULAR DEVICES AND METHODS
OF MAKING AND USING THE SAME
Docket No. : 1001.1738101
Customer No. : 28075

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By


JoAnn Lindman

Dear Sir:

Appellant respectfully requests a Pre-Appeal Brief Review of the pending application. A Notice of Appeal is filed herewith.

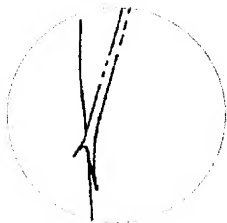
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Appellant has carefully reviewed the Final Office Action of June 26, 2008 and the Advisory Action of September 11, 2008. Currently claims 1-21 are pending in the application and claims 1-21 have been rejected by the Examiner. Appellant hereby requests a pre-appeal conference and file this pre-appeal brief concurrently with a Notice of Appeal. Favorable consideration of the claims is respectfully requested. Additionally, the proposed amendments filed in the After Final Amendment are not included in this

pre-appeal brief because the Examiner has entered them and because it is believed that the claims are allowable as entered. Appellants note that the Examiner's rejections of independent claim 1 have focused upon the issue of whether the anchors (50) of Walak et al. (U.S. Patent No. 6,540,767, hereinafter Walak) characterized by Walak as "sharp projections or barbs", may be said to provide the "cutting member disposed on the elongate member and generally facing toward the central axis" found in claim 1, reproduced in its entirety below:

1. An intravascular filter having a central axis comprising:
an elongate member;
an anchoring member for anchoring the intravascular filter to a vessel wall attached to the elongate member; and
a cutting member disposed on the elongate member and generally facing towards the central axis.

It has been the Examiner's position that the anchors (50) of Walak are capable of providing a "cut" within the definition supplied by the Examiner: "to penetrate with or as if with an edged instrument" while the Appellants have maintained that the barbs of the anchors would not provide a "cutting edge" as that term would be understood by one of ordinary skill in the art to which the invention applies, but rather are characterized by Walak as "sharp projections" which would be understood tend to partially pierce the vessel wall. The piercing action of the anchor would be limited by the adjacent structure of the strut, as illustrated in the detail of Figure 1 below, to prevent undesirable cutting or tearing of the vessel (vertical line to the left) with attendant bleeding into the surrounding tissue.



In focusing on the distinction between “cutting” and the partial penetration of the vessel wall by the barb of the anchor, both parties have neglected other features of the claims. In particular, pending claim 1 requires an elongate member having both “an anchoring member for anchoring the intravascular filter to a vessel wall” and “a cutting member disposed on the elongate member and generally facing towards the central axis”. Of these, Walak appears to mention only anchors, which necessarily face away from the central axis of the filter in order to engage the wall of the vessel. Walak does not mention a cutting projection, whether barbed or edged, which generally faces the central axis. Accordingly, the disclosure of Walak is limited to sharp penetrating barbs which form outward facing anchors and does not provide a separate cutting element, in addition to the anchors, specifically a cutting member which faces toward the central axis.

As will be seen in Figure 7, reproduced below, the cutting member blade (112) of the pending claims must face generally toward the central axis in order to provide its function, severing intima (124) which tends to encapsulate the tip of the elongate member (102) after the filter has been in place for sufficient time for neointimal hyperplasia to occur. Encapsulation makes it difficult to disengage anchor member (104) from the media (122) and the adventitia (120) of the vessel wall without tearing the intima thereby increasing trauma to the vessel wall. The cutting edge of the Examiner’s definition may be found in element (110) which faces generally inward as opposed to the barb of the anchoring element which faces generally outward as it must to engage the vessel wall.



Figure 7

As will be seen from the above discussion, Walak provides neither the inward facing cutting element nor any alternate inward facing structure which provides a similar function. For at least the reasons mentioned above, claims 1-5 and 13-21 are believed to be not anticipated by Walak and Appellant respectfully requests that the rejections be withdrawn.

Additionally, for similar reasons, as well as others, claims 2-21, which depend from claim 1 and include significant additional limitations, are believed to be patentable and nonobvious in view of Walak and Appellant respectfully requests that the rejections be withdrawn.

With regard to the Response to Arguments provided in the Final Office Action, the Examiner reproduced Figure 1 of Walak and asserted "the filter device of Walak has barbs that are facing inwardly. (The extension of the elongate member beyond the anchoring barb, which extension limits the penetration of the barb into the vessel wall is said to provide the inward facing barb.) These extensions are being interpreted as "cutting members" because they are fully capable of providing a 'cut'". Walak, at col. 4, lines 14-15 describes this region as follows: "Free end 40 of each wire of each wire 37 includes an anchor 50." Thus the ends of the wires are characterized solely as anchors. They do not appear to have any other identified structure or function. Further, the portion of the anchor in question is the end of the wire or elongate member and is not "a cutting member disposed on the elongate member". As is well known in this art, when the filter is collapsed for removal, the wire would have to be pulled sideways through the intima, if

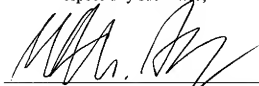
present, and the wire tip would not be positioned or shaped to cut in that direction. There is no mention of cutting, other than laser cutting, in Walak. Appellants point out that the penetrating barbs of the anchors clearly are facing outwardly, away from the central axis of the filter, as they must in order to engage the wall of the vessel in the deployed configuration of the filter. The Examiner has relied upon the definition of a "cut" provided by Merriam-Webster Online Dictionary (www.m-w.com) as involving an edged instrument. That same dictionary defines barb as: "a sharp projection with its point similarly oblique to something else". (Emphasis added.) In addition to facing generally 90 degrees from the required direction, *i.e.*, along the wall rather than inward toward the central axis of the filter, the portion of the wire end which has been identified by the Examiner as the "cutting" portion of anchor is indicated by reference numeral (50), said reference numeral being found only in Fig. 2, is specifically identified as the anchor of Walak. Thus Walak fails to disclose an elongate member having both an anchor and a cutting member. The portion of the anchor of Walak that is said to be capable of cutting is identified as an anchor, has no inward cutting edge, and is directed along the vessel wall and rather than inward toward the central axis. It is not a cutting member disposed on the elongate member.

In view of the foregoing, claims 1-21 are not anticipated by Walak and are nonobvious in view of Walak and the Examiner's rejections of claims 1-12 should be overruled. Issuance of a Notice of Allowance in due course is anticipated.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance, issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Date: Nov. 26, 2008



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